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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.								
10/510,912	10/08/2004	Osvaldo A Flores	21080P	6208								
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 11/30/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">LUCAS, ZACHARIAH</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1648</td><td></td></tr></table>		EXAMINER		LUCAS, ZACHARIAH		ART UNIT	PAPER NUMBER	1648	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/510,912	FLORES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-21 and 27-43 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,20,28,29 and 31-38 is/are rejected.
- 7) ☒ Claim(s) 21 and 39-43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 19-21 and 27-43 are pending in the application.
2. In the prior action, mailed on July 9, 2007, claims 18-21 and 27-43 were pending; with claims 27 and 30 withdrawn; claims 21, 39, and 43 objected to; and claims 18-20, 28, 29, 31-38, and 40-42 rejected.
3. In the Response of November 7, 2007, the Applicant cancelled claim 18 and amended claims 21 and 40.
4. Claims 19-21, 28, 29, and 31-43 are under consideration. With respect to claims 21 and 39-43, examination has not been extended to the non-elected species as there is currently no allowable generic claim.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. **(Prior Rejection- Withdrawn)** Claims 40-42 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claim 40 purported to depend from itself. In view of the amendment of claim 40, the rejection is withdrawn.

#### ***Claim Rejections - 35 USC § 102***

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7. **(Prior Rejection-Withdrawn)** Claims 18 was rejected under 35 U.S.C. 102(e) as being anticipated by De Francesco et al. (WO 02/059321). In view of the cancellation of the claim, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejection- Maintained)** Claims 18-20, 28, 29, 31-34, 37, and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over De Francesco (WO 02/059321) in view of WO 01/89364 (of record in the Office action of May 2007) and of Rice et al. (6,297,003); and further in view of Melnick et al. (U.S. 6,063,562) and Li et al. (U.S. 2004/0018529). Claim 18 has been cancelled from the application. The rejection is therefore withdrawn from this claim. The rejection is maintained against claims 19, 20, 28, 29, 31-34, 37, and 38.

The Applicant traverses the rejection on several basis.

First, the Applicant asserts that while De Francesco discloses that other HCV 3'UTRs can be used, the reference does not specifically mentioned, and that broad generic disclosures are not adequate to establish obviousness of the species. However, the Examiner is not relying only on such a broad disclosure to render obvious the species. Instead, the Examiner is relying on the teachings of De Francesco that indicate that any such UTR may be used, and a specific teaching disclosing the 3' UTR of HCV-1a (i.e. the Rice reference). As was indicated in the prior action,

Rice not only specifically teaches an HCV-1a 3' UTR, but also suggests the use of such for the construction of HCV replicons which could be used for screening for inhibitors of HCV replication. In making this argument, the Applicant has ignored the teachings of one of the references on which the rejection is based. It is noted that it is established law that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As the present argument addresses only the teachings of one of the cited references in the obviousness rejection based on a combination of references, the argument is not found persuasive.

Second, the Applicant also asserts that the Examiner has not provided any art indicating that the 3' UTRs of con-1 and HCV-1a are equivalent, and is relying only on his opinion without additional evidence. This argument is not found persuasive in view of the teachings of De Francesco which indicate that any "naturally occurring HCV 3' UTR and functional derivatives thereof" may be used. Page 10. Thus, the teachings of De Francesco indicate that the HCV 3' UTRs may act as functional equivalents for each other, and therefore provide adequate basis to render the use of any known HCV 3' UTR obvious to those of ordinary skill in the art in the compositions and methods of the reference.

The Applicant next argues the difference between wild-type and clinical isolate forms of NS5, and asserts that the teachings of Melnick and Li have nothing to do with the use of replicons. These arguments are not found persuasive. First, it is noted that the Applicant has ignored the teachings of the WO 01/89364 reference in there arguments. Second, while it is agreed that it is the obviousness of the invention as a whole that it at issue, the Examiner does

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not find persuasive the assertion that the rejection is based on impermissible hindsight. In making the rejection, the Examiner may rely on knowledge and motivations provided in the art. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). (indicating that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning and that so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper). The teachings of the WO 01/89364 reference, as well as those of Melnick and Li as described in the prior action indicate that those in the art would have been motivated to take enzymes from viral clinical isolates (including HCV as described in the WO 01/89364 reference). Moreover, while the teachings of Melnick and Li are not directly relevant to the claimed invention, they demonstrate a general motivation in the art to develop drugs against pathogens which develop resistance to known drugs during the course of infection. Thus, the Applicant's arguments are not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

10. **(Prior Rejection- Maintained)** Claims 35 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over De Francesco in view of Rice, WO 01/89364, Melnick, and Li as applied to claims 18-20, 28, 29, 31-4, 37, and 38 above, and further in view of Hawkins et al. (U.S. 5,783,669). Applicant traverses the rejection on substantially the same grounds as asserted with respect to the rejection above. The arguments are not found persuasive for the same reasons. The rejection is therefore maintained.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Double Patenting***

12. In the prior action, Applicant was advised that should claim 40 be found allowable, claim 42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicant made no arguments regarding this advisory.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **(Prior Rejection- Maintained)** Claims 18-20, 28, 29, 31-34, 37, and 38 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9 and 10 of copending Application No. 10/543,633. It is not Office policy to withdraw provisional rejections until a claim is allowed. The rejection is therefore maintained against claims 19-20, 28, 29, 31-34, 37, and 38. The rejection is withdrawn from cancelled claim 18.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

15. No claims are allowed. The replicon of SEQ ID NO: 2 appears to be allowable over the prior art. Claims 21, 39, and 43 are objected to for reading on non-elected inventions (i.e. SEQ ID NO:1).

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/  
Patent Examiner, AU 1648